

C. Remarks

The claims are 2-14 and 17-41, with claims 2, 19 and 20 being independent. Claim 16 has been cancelled without prejudice or disclaimer of subject matter and its recitations incorporated into claim 2. Applicants submit that no new matter has been added. Reconsideration of the present claims is respectfully requested.

Claims 2-14 and 16-18 stand rejected under 35 U.S.C. §103(a) as being obvious over Borkan (U.S. Patent No. 4,935,243) in view of Gonze (U.S. Patent No. 5,711,975) and Makino (U.S. Patent Application Publication No. 2003/0232076). Applicants respectfully traverse this rejection.

The present invention is directed to a gelatin capsule formed from a capsule film having a thickness not exceeding about 0.025 inches, and a capsule shell having an end composition comprising at least one gelatin, plasticizer and at least one hydroxypropylated starch, which is at least 50% ungelatinized. By virtue of this constitution, it is possible to provide high water content, chewable soft gelatin capsules with improved organoleptic properties. The present invention combines a multifactorial approach in modifying both the material of the capsule and the fabrication method of the encapsulation process in order to maximize the organoleptic properties of the capsule and the stability thereof. This includes manipulation of the origin, bloom strength, melting points and mixtures of gelatins, the use of hydroxypropylated, at least 50% ungelatinized starch as a water retention agent, the fabrication of thinner than expected gelatin films for use in the encapsulation process, only partial drying to a high end water content and dusting of the capsules with an anti-stickiness surface treatment agent.

It was traditionally thought that because chewable capsules are more delicate than swallowable capsules, for example, that it was not possible to make a commercially acceptable product with thin ribbons, as presently claimed. However, Applicants invented the claimed gelatin capsules, which are able to maintain both robust seals and thin ribbon walls (i.e., a thickness not exceeding about 0.025 inches) by virtue of the combination of stronger gelatins and hydroxypropylated, at least 50% ungelatinized starch. Page 3, paragraph [0033] of U.S. Patent Application Publication No. 2005/0136104 (“the ‘104 publication”). This is a surprising and unique aspect of the presently claimed invention. Further, as detailed in the specification, some embodiments of the subject invention allowed the rotary die encapsulation machine to be run at speeds up to 3.5 RPM, well above the traditional limits of about 2.0 RPM seen with other soft chewable capsule formulations. *Id.*

Further, tasters report that the thin film capsules generally have improved organoleptic properties, such as superior mouth texture, enhanced ease of dissolution, and less feel of gelatin mass. Page 12, paragraph [0072] of the ‘104 publication.

Borkan discloses a chewable softgel capsule containing gelatin and a plasticizer (including glycerol); however, as noted by the Examiner, in part, Borkan does not teach or suggest 1) the inclusion of a modified starch, such as hydroxypropylated starch, 2) that the starch is at least 50% ungelatinized, or 3) a capsule having a film thickness not exceeding about 0.025 inches.

The Examiner has again alleged that Borkan discloses bloom strengths in the range 60-300. However, Borkan fails to suggest the benefits conferred by use of the specific types of gelatins, including the importance of high bloom strength to increase ribbon strength, capsule seal strength and resistance to deformation at higher temperatures,

which are all important attributes of the present invention. Therefore, Applicants submit that Borkan does not render the present invention obvious.

Gonze does not remedy the deficiencies of Borkan. Gonze is cited by the Examiner for allegedly teaching an ungelatinized hydroxypropyl tapioca starch for use in sugar-free confectionery products. However, Gonze fails to teach or suggest using a hydroxypropylated starch, let alone that the starch is over 50% ungelatinized, as part of a chewable capsule composition. Gonze is limited to a disclosure of ungelatinized hydroxypropyl tapioca starch in gums and pastilles. Still further then, Gonze does not teach or suggest using the ungelatinized starch to produce thinner ribbons having improved organoleptic properties. One of ordinary skill in the art would not have combined the ungelatinized hydroxypropyl tapioca starch of Gonze with the chewable softgel capsule of Borkan to arrive at the present invention.

Likewise, Makino does not remedy the deficiencies of Borkan and Gonze. Makino is cited for allegedly teaching soft gelatin capsules comprised of partially gelatinized starch and a water content between 8% to 25%. In addition, Makino is cited for disclosing casting ribbons with a thickness of 0.028-0.029 inches. While Applicants maintain that there are numerous grounds upon which the present invention can be distinguished from the combined disclosure of Borkan, Gonze and Makino, as amended herein, the claims recite a capsule having a film thickness not exceeding about 0.025 inches, which further distinguishes the present invention. Makino fails to teach or suggest that such thinner ribbons may be used in a chewable soft capsule.

Further, additional benefits of the subject invention over Makino are disclosed at paragraph [0073] of the '104 publication. As explained therein, tasters

preferred the capsules of the instant invention over those fabricated according to Makino. Further, the capsules of the instant invention displayed a 26.8% expansion during softening, compared with a 0.7% expansion during softening for the Makino capsules, which may, in part, account for the superior organoleptic qualities of the capsules of the subject invention. Still further, the instant capsules displayed softening over a range of 34-139°C, compared to a softening range of 44-77°C for the Makino capsules. Accordingly, it is clear that Makino fails to remedy the deficiencies of Borkan and Gonze.

In sum, the presently claimed invention is not rendered obvious by the cited references, whether considered separately or in any permissible combination. The references simply do not teach or suggest the combination of features of the presently claimed invention, e.g., a capsule having a film thickness not exceeding about 0.025 inches and hydroxypropylated, at least 50% ungelatinized starch in about 5-35 weight %. This combination of features results in a capsule shell having improved organoleptic properties, including mouth feel and dissolution/disintegration of the shell, and improved physical stability. For at least the reasons set forth above, Applicants submit that the present invention is not rendered obvious and respectfully request withdrawal of the §103 rejection.

In view of the foregoing amendments and remarks, Applicants respectfully request favorable reconsideration and early passage to issue of the present application. Should the Examiner believe that issues remain outstanding, the Examiner is respectfully requested to contact Applicants' undersigned attorney in an effort to resolve such issues and advance the case to issue.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our address given below.

Respectfully submitted,

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